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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,498	11/15/2000	Chaoying Zhao	014938.0003	4672

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/713,498

Applicant(s)
Zhao

Examiner
Pak, J.

Art Unit
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 9, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other:

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Claims 1-7 are pending in this application.

Applicant's election with traverse of a single disclosed species containing sodium chloride, sodium bicarbonate, calcium lactate, hydroxyethyl starch, dextran and gelatin derivatives in Paper No. 8 (2/19/02) is acknowledged. Applicant is advised that the following expanded elected subject matter will be included in the examination on the merits – any combination of sodium chloride and hydroxyethyl starch. The claims will presently be examined to the extent that they read on the expanded elected subject matter. Applicant traverses to the extent that the prior art must be closer than non-elected subject matter. It is so noted.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) In claim 1, it is unclear whether the percentages recited in the claims are intended for single individual ingredients or for the total of a mixture of ingredients.

(2) In claim 1 and elsewhere, proper nomenclature should not recite a double dash mark for chemical nomenclature or numerical dashes.

(3) In claim 1, phrase “as well as the remainder of conventional injections” is improper and informal. It is also unclear as to what is considered the metes and bounds of “conventional injections” (claim 1 and elsewhere).

(4) In claim 7, there is an extra period in the eleventh line of the claim.

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(5) In claim 7, "proportion described above" is improper referential language.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 98/08500.

WO 98/08500 explicitly discloses a hypertonic composition comprising L-arginine, sodium chloride (including 6 wt%, see claim 14) and hetastarch (hydroxyethyl starch, minimum 5 wt%, see Table 3). See claims 1-3, 6-7, 10-11, 13-14. Applicant's claim 1 is therefore anticipated or at the very least rendered obvious within the meaning of section 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/08500.

WO 98/08500 explicitly discloses a hypertonic composition comprising L-arginine, sodium chloride (including 6 wt%, see claim 14) and hetastarch (hydroxyethyl starch, minimum 5 wt%,

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see Table 3). See claims 1-3, 6-7, 10-11, 13-14. Lowering the hypertonicity of the saline from 7.5% is suggested (see page 7, line 22 to page 8, line 2).

While specific MW of hydroxyethyl starch and specific mixing steps are not expressly disclosed by the cited reference, the ordinary skilled artisan would have been motivated to utilize well known, physiologically acceptable hydroxyethyl starch, which have the physical characteristics that are recited in the claims, and the ordinary skilled artisan would also have been motivated to mix the ingredients to formulate an injectable, physiologically acceptable solution. Claimed concentrations of NaCl and hydroxyethyl starch clearly overlap with those of the cited reference, and the reference also suggests an advantage of lower than 7.5% saline.


Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been fairly suggested by the teachings of the cited reference.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


JOHN PAK
PRIMARY EXAMINER
GROUP 1600